



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,539	10/04/1999	LOUIS S. KUCERA	0044317U3	9782

28977 7590 07/30/2002

MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 07/30/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/412,539

Applicant(s)
KUCERA et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-71, 95, 96, and 103-109 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-71, 95, 96, and 103-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 56-71, 95, 96 and 103-109 are pending in the application.

This action is in response to applicants' amendment and RCE filed May 7, 2002.

Response to Arguments

Applicant's arguments filed May 7, 2002 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled d) and f) maintained in the office action mailed October 31, 2001 which are hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 56-71 and 96, the applicants' remarks concerning the enablement of the compounds of formula III is acknowledged but not found persuasive. The applicants' stated that the specification describes how the Z moiety of Formula III has demonstrated anti-viral activity by itself and its conjugation to the remainder of the molecule of Formula III provides multiple active sites for viral inhibition see page 11, lines 4-7 and pages 12, lines 3-6; sets forth the efficacy on page 14, line 20 through page 15, line 8; provides dosage ranges on page 18, lines 14-17 and page 15, lines 15-17 and lines 26-29. The applicants' also point to the exemplary preferred compound of Formula III, 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine. However, this compound, not ion, is not with in the genus of Formula III. Specifically, the "ions" of Claims 56 and 95 are such that the Z

Art Unit: 1624

moiety is bonded directly to the phosphorus atom not through an oxygen atom as shown by the applicants' exemplified "compound". As stated in previous office actions, the specification does not have any working examples on the use of the ionic compounds of Formula III. The absence of working examples is one of the factors to be considered in deciding whether the practice of an invention would involve undue experimentation. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of viral infections.

It is also noted that in view of the lack of working examples it is not known how to make the ions of Formula III, thus claims 95, 96, 108 and 109 are included in the rejection.

Claims 56-71, 95, 96 and 103-109 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

In view of the amendment and filing of an RCE on May 7, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

3. Claims 56-71, 95, 96 and 103-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 56-71, 95, 96 and 103-109 are vague and indefinite in that it is not known what is meant by the compounds of formula III, which contain an oxygen atom with a negative charge, however, it is not seen where the balancing positive ion is. Ex parte Diamond (POBA 1959) 123 USPQ 167.
- b) Claims 56-64, 67-71, 103, 104 and 107 are vague and indefinite in that it is not known what is meant by the definition of X which is missing part of the last moiety. It is believed that the applicants intended NCH_3 .
- c) Claims 56-67, 69-71, 95, 96 and 103-109 are vague and indefinite in that it is not known what is meant by the comma which appears after the structure of formula (V) and before the (V) on pages 3 and 4 of the amendment.
- d) Claim 68 recites the limitation "guanine, xanthine and hypoxanthine" in the definition of B. There is insufficient antecedent basis for this limitation in the claim. Guanine and hypoxanthine require a substituent $=\text{O}$ at the 6 position and xanthine requires a substituent $=\text{O}$ at the 2 and 6 position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner

Art Unit: 1624

can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brenda Coleman

Brenda Coleman
Primary Examiner AU 1624
July 26, 2002